

Applicants: Mitchell Shirvan and Meir Bialer  
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Remarks

Claims 1-96 were pending in the subject application. By this amendment, applicants have canceled claims 11-46 and 48-92, amended claims 1, 47 and 93-96 and add new claims 97-101. Consequently, claims 1-10, 47 and 93-101 are currently pending.

The above-identified application is a continuation of U.S. Serial No. 09/932,370, filed August 17, 2001. A Final Office Action was issued in connection with U.S. Serial No. 09/932,370 on June 18, 2003. On December 18, 2003, applicants filed a Notice of Appeal and Petition for Three Month Extension of Time in connection with U.S. Serial No. 09/932,370. Consequently an Appeal Brief was due February 18, 2004 in connection with U.S. Application No. 09/932,370. Applicants are concurrently filing a petition for a two-month extension of time. Accordingly, an Appeal Brief is now due April 18, 2004 in connection with U.S. Application No. 09/932,370. Consequently, U.S. Application No. 09/932,370 is copending with this continuation and this continuation is being timely filed.

INFORMATION DISCLOSURE STATEMENT

In accordance with their duty of disclosure under 37 C.F.R. §1.56, applicants would like to direct the Examiner's attention to the following references, which are listed on Form PTO-1449 (**Exhibit A**). A copy of each of the documents listed below as items 4, 24 and 25 is attached hereto as **Exhibits 1-3** respectively.

This Information Disclosure Statement is being submitted pursuant to 37 C.F.R. §1.97(b)(3) before the mailing of a first Office Action on the merits. Thus, this Information Disclosure Statement should be entered and considered.

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Applicants note that the reference listed as item 24 was cited in a Supplementary European Search Report in a corresponding European application. A copy of the Supplementary European Search Report is attached hereto as **Exhibit B**.

The above-identified application claims benefit under 35 U.S.C. §120 of Serial No. 09/932,370, filed August 17, 2001. In accordance with 37 C.F.R. §1.98(d), copies of the documents listed below which have previously been submitted to, or cited by the U.S. Patent Office in connection with Serial No. 09/932,370 are not provided.

In addition, applicants note that pursuant to the Notice appearing in the August 5, 2003 Official Gazette, as this application is being filed after June 30, 2003, copies of the disclosed U.S. Patents are not provided.

1. U.S. Patent No. 4,639,468, issued January 27, 1987, Roncucci et al.;
2. U.S. Patent No. 4,699,927, issued October 13, 1987, Deboeck;
3. U.S. Patent No. 4,913,906, issued April 3, 1990, Friedman et al.;
4. Re-examination certificate of U.S. Patent No. 4,913,906 (**Exhibit 1**);
5. U.S. Patent No. 4,301,176, issued November 17, 1981, Grabowski et al.;
6. U.S. Patent No. 5,169,642, issued December 8, 1992 (Brinker

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et al.);

7. U.S. Patent No. 5,585,358, issued December 17, 1996, Bialer et al.;
8. U.S. Patent No. 5,945,416, issued August 31, 1999, Shannon et al.;
9. U.S. Patent No. 5,760,007, issued June 2, 1998, Shank et al.;
10. U.S. Patent No. 6,287,598, issued September 11, 2001 (Ayer et al.);
11. U.S. Patent No. 6,319,903, issued November 20, 2001, Carrazana et al.;
12. U.S. Patent No. 6,251,946, issued June 26, 2001, Vinikova et al.;
13. U.S. Patent No. 6,268,396, issued July 31, 2001, Nau et al.;
14. Belgian Patent Application No. 885.303, published September 19, 1980, Roncucci et al.;
15. Canadian Patent No. 1 208 230, issued July 22, 1986, Chambon et al.;
16. European Patent Application No. 0 046 707, published March 3, 1982, Chambon et al.;
17. European Patent Application No. 0 250 997, published July

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- 1, 1988, Chiesi et al.;
18. European Patent Application No. 0 442 012, published August 21, 1991, Friedman et al.;
19. European Patent Application No. 0 659 174, published October 2, 1999, Bialer et al.;
20. French Patent Application No. 2 531 950, published August 19, 1983, Cordi et al.;
21. Great Britain Patent No. 2 126 224, published March 21, 1984 Cordi et al.;
22. Soviet Union Patent Application No. 988188, published January 7, 1983;
23. PCT International Application PCT/US87/02347 (WO 88/01861), published March 24, 1988;
24. PCT International Application No. WO 95/01956, published January 19, 1995 (**Exhibit 2**);
25. Irish 52415, published October 28, 1987 (**Exhibit 3**);
26. Bialer, "Clinical Pharmacology of Valpromide", Clinical Pharmacokinet., 1991, 20(2): 114-122;
27. Bialer et al., "Pharmacokinetics of a Valpromide Isomer, Valnoctamide, in Healthy Subjects", Eur. J. Clin. Pharmacol., 1990,38:289-291;

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28. Buzzi et al., "The Antimigraine Drug, Sumatriptan (GR43175), Selectively Blocks Neurogenic Plasma Extravasation from Blood Vessels in Dura Mater", Brit. J. Pharmacol., 1990, 99: 202-206;
29. Granneman et al., "Aspects of the Metabolism of Valproic Acid", Chem. Abstracts, 1984, 101(17): 143458;
30. Granneman, "Aspects of the Metabolism of Valproic Acid", Xenobiotica, 1984, 14(5): 375-387;
31. Hadad et al., "Pharmacokinetic Analysis of Ester Prodrugs of Valproic Acid," J. Pharm. Sci., 1992, 81(10): 1047-1050;
32. Hansen, H.C., *Southern Medical Journal* (1999) 92(7):642-649;
33. Haj-Yehia et al., "Structure-Pharmacokinetic Relationships in a Series of Valpromide Derivatives with Antiepileptic Activity", Pharm. Research, 1989, 6(8): 683-689;
34. Kim et al., "An Experimental Model for Peripheral Neuropathy Produced by Segmental Spinal Nerve Ligation in the Rat", Pain, 1992, 50: 355-363;
35. March, *Advanced Organic Chemistry*, 3<sup>rd</sup> Edition, 1985, 354-355, 368, 377-379;
36. McQuay, H. et al., *BMJ* (1995) 311: 1047-1052;
37. Magnus, L., *Epilepsia* (1999) 40(Suppl. 6): S66-S72;

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38. Zakrzewska, J.M. et al., Pain (1997) 73: 233-230;
39. Yu et al., "Simultaneous Delivery of Valproic Acid and Glycine to the Brain", Neuropath., 1991, 15(1): 37;
40. "Milacemide", Drugs of the Future, 1984, 9(8): 587-588; and
41. "Milacemide", Drugs of the Future, 1991, 16(8): 775.

Applicants request that the Examiner review the references and make them of record in the subject application.

No fee, other than the enclosed filing fee, is deemed necessary in connection with the filing of this Preliminary Amendment and Information Disclosure Statement. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



John P. White  
Registration No. 28,678  
Gary J. Gershik  
Registration No. 39,992  
Attorneys for Applicants  
Cooper & Dunham LLP  
1185 Avenue of the Americas  
New York, New York 10036  
(212) 278-0400